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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/606,219	06/29/2000	Ivan Tomka	24301	7685

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WASHINGTON, DC 20005

EXAMINER

NORDMEYER, PATRICIA L

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 05/09/2002

7

Please find below and/or attached an Office communication concerning this application or proceeding.

MF=7

Office Action Summary

Application No.

09/606,219

Applicant(s)

TOMKA ET AL.

Examiner

Patricia L. Nordmeyer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-11 and 22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims 12 - 21 in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the classes and subclasses cited for each of the groups belong to the Examiner's art unit, examination of all the claims would not pose a serious burden and the method and apparatus are related to the article since it describe how the article is made. This is not found persuasive because the method group and apparatus group classes and subclasses are not examined by the Examiner's art unit. The Examiner's art unit (1772) only examines class 428. Class 264 is examined by Art Units 1711, 1732 and 1731. Class 53 is examined by Art Unit 3721. It would it be to the Applicant's benefit to have the method and apparatus claims examined by an Examiner more knowledgeable in the art of making the starch mass.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "strength σ_m " in claim 19 is unclear, which renders the claim vague and

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indefinite. It is unclear from the claim language what is meant by the symbol, if it is trying to be specific in the way the weight was tested, or if it is just a symbol that represents the measurement of weight in general.

4. Claim 21 recites the limitation "at least two films have a different chemical composition" in a shape body consisting of a multi-layered film. There is insufficient antecedent basis for this limitation in the claim. There is no mention of film in the shape body claims.

5. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 12 recites the broad recitation "the limiting viscosity of the homogenized mass is at least 40 ml/g", and the claim also recites "preferably at least 50 ml/g and even more preferably at least 60 ml/g" which is the narrower statement of the range/limitation.

In the present instance, claim 15 recites the broad recitation “a weight ratio of 1:1.5”, and the claim also recites “preferably 1:1.2 and even more preferred 1:1” which is the narrower statement of the range/limitation.

In the present instance, claim 16 recites the broad recitation “in a weight range of 3.5% by weight to 15% by weight”, and the claim also recites “preferably of 5% by weight to 8% by weight” which is the narrower statement of the range/limitation.

In the present instance, claim 18 recites the broad recitation “an elongation at rupture of at least 100%”, and the claim also recites “preferably at least 160% and even more preferable 240%” which is the narrower statement of the range/limitation

In the present instance, claim 19 recites the broad recitation “a strength of at least 2 MPa”, and the claim also recites “preferably a strength in the range of 3.5 to 8 MPa and even more preferred from 4 MPa to 6.5 MPa” which is the narrower statement of the range/limitation.

In the present instance, claim 20 recites the broad recitation “a thickness in the region between 0.1 and 2 mm”, and the claim also recites “preferably between 0.2 to 0.6 mm” which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 12, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Bastioli et al. (USPN 5,462,980).

Bastioli et al. discloses a starch composition containing 30 to 80% by weight amylopectin material with respect to the starchy and thermoplastic components (Column 3, lines 8 – 12), an organic softener made of 5 to 25% by weight of glycerine (Column 3, lines 44 – 51) and esters of fatty acids as release agents and lubricants (Column 4, lines 37 – 31). Since Bastioli et al. contains the selected materials of amylopectin and glycerine, it is inherent that the starch would have a viscosity of at least 40 ml/g.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bastioli et al. in view of Nakajima et al. (USPN 5,098,606).

Bastioli et al. discloses the claimed starch mass above except for the mass containing

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glycerine monostearate and lecithin in a weight ratio of 1:1.5, preferably 1:1.2, and even more preferred 1:1.

Nakajima et al. teaches a phospholipid, lecithin, (Column 3, lines 14 – 20) and glycerine monostearate as a nonionic surfactant (Column 3, lines 21 – 28) in a ratio of a phospholipid to surfactant of 9.5:0.5 to 1:9 (Column 3, lines 54 – 56) in a emulsified composition used for the administration of drugs for the purpose of incorporating the drug quickly into the body from the blood stream of the patient.

It would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to have provided the lecithin and glycerine monostearate in Bastioli et al. in order to incorporate the drug quickly into the body from the blood stream of the patient as taught by Nakajima et al.

Nakajima et al. discloses the claimed invention except for the weight ratio of 1:1.5, preferably 1:1.2, and even more preferred 1:1 of glycerine monostearate and lecithin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to change the weight ratio of the glycerine monostearate and lecithin, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges through routine experimentation depending on the end results involves only routine skill in the art. *In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980).

10. Claims 16, 17 and 21 rejected under 35 U.S.C. 103(a) as being unpatentable over Bastioli et al. in view of Wittwer et al. (USPN 4,673,438).

Bastioli et al. discloses the claimed starch mass above except for the mass additionally

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containing an aggregate in a weight range of 3.5% by weight to 15% by weight with respect to the total weight of the mass, preferably of 5% by weight to 8% by weight, wherein the aggregate is selected from the group consisting of carbonates and/or hydrogen carbonates of alkali and/or earth alkali ions, preferably calcium carbonate, amylases, further decomposing agents colorings, preservatives, antioxidants, physically and/or chemically modified biopolymers and vegetable polypeptides, a shape body manufactured from a mass according to claim 12 and wherein the shape body consists of a multi-layered film and that at least two of the films have a different composition.

Wittwer et al. teaches films containing starches, plasticizers, lubricants and colorings in concentrations of 0.001 to 10% based on the weight of the starch (Column 13, lines 63 – 67) in capsules (Column 13, lines 42 – 47) for the purpose of packaging drugs in colored capsules that help identify the drugs before being ingested by the patients.

It would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to have provided the colorings with the selected weight percentage in Bastioli et al. in order to packaging drugs in colored capsules that help identify the drugs before being ingested by the patients as taught by Wittwer et al.

11. Claims 18 – 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bastioli et al. (USPN 5,462,980) in view of Wittwer et al. (USPN 4,673,438) as applied to claims 16, 17 and 21 above, and further in view of Bastioli et al. (USPN 5,569,692).

Bastioli et al ('980) , as modified with Wittwer et al., discloses the claimed invention

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except for an elongation of rupture of at least 100%, preferably at least 160%, and even more preferred 240% at 25 C and 60% relative air humidity, the body shape with a strength of at least 2 MPa, preferably a strength in the range of 3.5 MPa to 8 MPa and even more preferred from 4 MPa to 6.5 MPa and a capsule with a thickness between 0.1 and 2mm, preferably between 0.2 and 0.6 mm.

Bastioli et al. ('692) teaches a breaking strain of 207%, a breaking stress of 21 MPa, both at a temperature of 23 C and 55% relative humidity (Column 48 – 59) and a thickness of 0.02mm (Column 4, lines 11 – 12) in a film or molded article formed of starch containing amylopectin for the purpose of forming a biodegradable film or article with good chemical, mechanical and chemical properties.

It would have been obvious to one of ordinary skill in the art at the time the applicant's invention was made to have provided the breaking strain, breaking stress and thickness in the modified Bastioli et al. ('980) in order to form a biodegradable film or article with good chemical, mechanical and chemical properties as taught by Bastioli et al. ('692).

Bastioli et al. ('692). discloses the claimed invention except for the thickness between 0.1 and 2mm and the strength between 2 and 8 MPa. It would have been obvious to one having ordinary skill in the art at the time the invention was made to change the thickness of the film which would affect the strength, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges through routine experimentation depending on the end results involves only routine skill in the art. *In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia L. Nordmeyer whose telephone number is (703) 306-5480. The examiner can normally be reached on Monday thru Friday from 8:15 a.m. until 4:45 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Y. Pyon can be reached on (703) 308-4251. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Patricia L. Nordmeyer
Examiner
Art Unit 1772

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pln
May 1, 2002

Harold Pyon
HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

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